



DEPARTMENT OF HEALTH AND HUMAN SERVICES

92062d
Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
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December 19, 2001

**VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

In reply refer to Warning Letter SEA 02-21
John H. Cao, President/Owner
King's Oriental Foods Company
1238 South Weller Street
Seattle, Washington 98144

WARNING LETTER

Dear Mr. Cao:

We inspected your firm located at 1238 South Weller Street, Seattle, Washington, on November 7-8, & 13, 2001, and found that you have serious deviations from Title 21 of the Code of Federal Regulations (21 CFR) Part 123 - Fish and Fishery Products (Seafood HACCP regulations) and (21 CFR) Part 110 - Good Manufacturing Practices regulations. A FDA 483 form (copy enclosed) listing the deviations was presented to you, some of which were previously brought to your attention, cause your stored and processed food products to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act and the Seafood HACCP regulations through links in FDA's homepage at www.fda.gov.

The Seafood HACCP deviations were as follows:

1. You must have a written HACCP plan to control for any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(b). Your firm does not have a HACCP plan for your rice rolls containing dried shrimp to control for the food safety hazard of pathogens.
2. You must adequately monitor sanitation conditions and practices during processing, to comply with 21 CFR 123.11(b). Your firm did not monitor the eight areas of sanitation as evidenced by the insanitary conditions listed below. The eight areas of sanitation are as follows:
 - a. Safety of water
 - b. Condition and cleanliness of food contact services
 - c. Prevention of cross contamination

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- d. Maintenance of hand washing, hand sanitizing, and toilet facilities
- e. Protection of food from adulterants
- f. Proper labeling, storage, and use of toxic compounds
- g. Control of employee health conditions
- h. Exclusion of pests

The following is a list of the insanitary conditions observed by our investigators during the inspection:

1. Rodent activity in the facility:
 - a. A lot of 30-pound boxes of Crown Brand Chantaboon Rice Sticks stored on a pallet in the center of the warehouse had several fluorescing stains and numerous rodent excreta pellets on box surfaces.
 - b. A lot of 50-pound boxes of Preserved Whole Radishes from Thailand stored on a pallet in the center of the warehouse had several fluorescing stains and numerous rodent excreta pellets on box surfaces.
 - c. Five dead rodents were found on glue boards and catch all traps in several areas of your facility demonstrates you have an active rodent problem. Furthermore, one of these dead rodents was found in the processing area and was decomposed.
 - d. Numerous rodent excreta pellets were found at floor/wall junctures in several areas of the warehouse and processing area.
 - e. Numerous rodent excreta pellets were found on pallet boards, underneath pallets of food products and on shelves in the processing area in close proximity to packaged finished product.
2. Bird activity in the facility:
 - a. Live birds flying in the warehouse and over the processing area during production of food products. Birds were landing on top of a pallet of styrofoam trays used to package finished product.
 - b. Bird excreta was found on the outer containers of two lots of rice sticks stored in the warehouse.

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3. Poor employee practices, sanitation practices, and structural deficiencies evidenced by the following:
 - a. Employee picked up a stack of rice wrappers from the floor, brushing off with hands, then packaging them.
 - b. Condensation from a steam flume was dripping onto an uncovered vat of rice.
 - c. Build up of mold and mildew on south wall of processing area.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations, and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations. We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as your revised HACCP plan and copies of your monitoring records, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

Please send your reply to the Food and Drug Administration, Attention: Lisa M. Elrand, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021. If you have questions regarding any issue in this letter, please contact CO Elrand at (425) 483-4913, or email her at lelrand@ora.fda.gov.

Sincerely,



Charles M. Breen
District Director

Enclosures:
Form FDA 483

cc: WSDA with disclosure statement